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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,138	01/31/2002	Alan Alexander Wilson	BEP 3002	5987

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KRAMER & AMADO, P.C.  
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ARLINGTON, VA 22202

EXAMINER

HARTLEY, MICHAEL G

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 10/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/059,138

Applicant(s)

WILSON ET AL.

Examiner

Michael G. Hartley

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Jewell (New Trends...Radiopharm. Syn., 1991, 6-PTO-1449).

Jewett discloses a method of radiolabeling a precursor compound comprising injecting into an injection loop of a HPLC a chemical precursor compound (either PK1185 or flumazenil) and a radiolabeling agent ( $^{11}\text{C}$ -methyl iodine), allowing the precursor compound and radiolabeling agent to react, injecting into the HPLC column and isolating the compound, see summary and pages 388-390. The precursor compound is in a solvent and includes a basic catalyst, see summary. The reaction time is within the claimed time frame, about 3-6 minutes. A radiolabeled compound is formed via said process, which would be the same as the radiolabeled compound in claims 9 and 10.

Claims 1-4, 6, 7, 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Watkins (Appl. Radiat. Isot. Vol 39, No. 5, 1988, 17-PTO-1449).

Watkins discloses a method of radiolabeling a precursor compound comprising injecting into an injection loop of a HPLC a chemical precursor compound (1-desmethyl-4'-chlorodiazepam) and a radiolabeling agent ( $^{11}\text{C}$ -methyl iodine), allowing the precursor compound and radiolabeling agent to react, injecting into the HPLC column and isolating the compound, see pages 441-443. The precursor compound is in a solvent (acetone), see abstract. The reaction time is within the claimed time frame, about 5 minutes. A radiolabeled compound is formed via said process, which would be the same as the radiolabeled compound in claims 9 and 10.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Watkins (Appl. Radiat. Isot. Vol 39, No. 5, 1988, 17-PTO-1449).

Watkins discloses a method of radiolabeling a precursor compound comprising injecting into an injection loop of a HPLC a chemical precursor compound (1-desmethyl-4'-chlorodiazepam) and a radiolabeling agent ( $^{11}\text{C}$ -methyl iodine), allowing the precursor compound and radiolabeling agent to react, injecting into the HPLC column and isolating the compound, as set forth above.

Watkins fails to disclose that the precursor compound is an acid salt or the use of a catalyst; however, the use of both are well known in the art, as shown by Dannals (Quant. Imag., 1990, 2-PTO-1449).

Dannals teaches methods of radiolabeling precursor compounds using methods that are analogous to those of Watkins, wherein the precursor compound is an acid salt and a catalyst is employed to aid in the reaction, see, for example, Fig. 5, page 28. The method provides a rapid, reproducible synthesis for preparing an very useful radiopharmaceutical, see page 27.

It would have been obvious to one of ordinary skill in the art to use both an acid salt precursor and/or catalyst in the methods of radiolabeling disclosed by Watkins because both are well known to provide advantages in methods of radiolabeling. For example, starting with an acid precursor is known to provide a useful radiopharmaceutical (carfentanil) and enables a rapid and reproducible synthesis using HPLC, as shown by Dannals, which also teaches that the use of a catalyst can provide the clear advantage of increasing the reaction rate.

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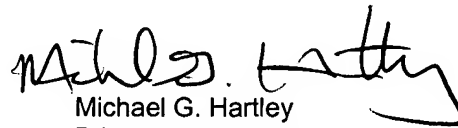
**Conclusion**

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (703) 308-4411. The examiner can normally be reached on M-F, 7:30-5, off alternative Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.



Michael G. Hartley  
Primary Examiner  
Art Unit 1616

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